

## Title: Improved Ear Coupler

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## BACKGROUND OF THE INVENTION

## 1.) Field of the Invention

The present invention relates to ear couplers or earphones that cover the ear to create a desired acoustic environment.

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## 2.) Background of the Invention

It is inherently difficult to determine hearing impairment in infants, since they cannot participate in traditional hearing tests which require subjects to indicate whether they can hear various sounds. However, if hearing impairment is not detected until the infant grows into a toddler or child, then the potential for long-term disability increases, since the child's language skills will have developed before remedial measures have been undertaken. The optimal time to screen for hearing impairment is immediately after birth, both because early detection allows for early treatment, and because parents often fail to bring their children in for later appointments.

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Devices and methods have been developed to evaluate infant hearing by subjecting an infant to an aural stimulus, and then measuring the electroencephalographic or otoacoustic response to that stimulus. These devices and methods depend on the creation of the proper acoustic environment about the subject's ear, so that ambient noise does not interfere with the hearing evaluation, and so that the stimulus has the appropriate duration, amplitude, and frequency content.

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1 To create the desired acoustic environment, earphones or ear couplers have been  
used. Information relevant to previous ear couplers can be found in U.S. Patent Nos.  
5,826,582, 4,930,520, and in U.S. Patent Application No. 09/395,799. Although many of  
these devices have worked well, they can sometimes become detached from the  
5 subject's head, because of the variable and irregular surfaces surrounding the ear, and  
because infants tend to move during testing. Additionally, with previous ear couplers,  
the assembly that houses the stimulus-producing transducer tends to tug the ear  
coupler away from the ear. Existing ear couplers are also relatively expensive to  
manufacture, in part because they require production or assembly of more than one  
part.

10 It is therefore desirable to construct an ear coupler that is better able to remain  
attached to the subject's head, and that is not subject to being tugged off the head by  
forces acting on the transducer housing. It is also desirable to design a one-piece ear  
coupler that can be inexpensively manufactured by injection molding or other suitable  
processes.

15 3.) Brief Summary of the Invention

20 The present invention is a transparent one-piece ear coupler, with an internal  
chamber that creates a tuned acoustic environment about the subject's ear, with a port  
to accommodate a transducer, and with a flange positioned around the periphery of the  
coupler to attach the coupler to the subject's head.

25 Other features of the preferred embodiment of the present invention include a  
tab to facilitate removal of the ear coupler, and a mark or target on the coupler to help  
ensure proper alignment over the subject's ear. The coupler is generally D-shaped, and  
is designed so as to fit on either ear. Preferably, the coupler is made of transparent  
Rimflex® thermoplastic elastomer, although other flexible, transparent materials could  
be used. The bottom wall of the coupler contains waffle-shaped or other surface

1 features, which add rigidity and create the desired acoustic characteristics of the  
chamber.

5 The exterior wall of the coupler is ribbed to provide means to securely lock in place the housing that contains the transducer. The side of the flange in contact with the skin contains hydrogel or another adhesive substance to stick to the subject's head. The interior surface of the flange may also contain waffle-shaped or other surface features for improved adhesion of the hydrogel to the Rimflex®, although no such extrusions are provided in the preferred embodiment of this invention. The walls of the coupler are of sufficient thickness to resist crushing, and to provide the desired acoustic environment about the subject's ear.

10 The housing that contains the transducer, known as an acoustic transducer assembly (ATA), securely and positively fits into the port that enters into the internal chamber. The ATA latches onto ribs on the sides of the coupler, and can be rotated up or down while in use, so that the length of the ATA can be placed either above or below the center of the coupler.

15 Before being attached to the subject's head, the ear couplers are attached to release paper. Preferably, the adhesive that secures the ear couplers to the release paper (and to the subject's head) is a hydrogel, which can be selectively applied only to the flange of the ear coupler during manufacture, thereby minimizing waste. There are holes in the release paper, centered over the chamber of the ear coupler, to help the  
20 user hold the coupler while the ATA is being inserted.

25 In operation, the ATA is inserted into the port, and the ear coupler is removed from the release paper and placed on the subject's ear. The adhesive on the flange sticks to the subject's head, and because of the unique features of the invention as disclosed herein, the ear coupler will tend to stay affixed to the infant's head, even if he or she moves during testing. The tab helps remove the ear coupler from the release paper, and helps remove it from the subject's head when the testing is complete.

1 4.) Brief Description of the Drawings

Figure 1 is an elevated perspective view of the ear coupler in accordance with a preferred embodiment of the present invention.

Figure 2 is an elevated perspective view of the ear coupler in accordance with a preferred embodiment of the present invention, from the opposite side as Figure 1.

5 Figure 3 is a bottom elevated perspective view of the ear coupler in accordance with a preferred embodiment of the present invention.

Figure 4 is a top plan view of the ear coupler in accordance with a preferred embodiment of the present invention, with the ATA.

10 Figure 5 is a side view of the ear coupler with the ATA in accordance with a preferred embodiment of the present invention.

Figure 6 is a side view, from a different perspective than Figure 5, of the ear coupler with the ATA in accordance with a preferred embodiment of the present invention.

15 Figure 7 is an elevated side perspective view of the ear coupler in accordance with a preferred embodiment of the present invention, with the ATA.

Figure 8 is an elevated side perspective view of the ear coupler in accordance with a preferred embodiment of the present invention, with the ATA, from the opposite perspective of Figure 7.

20 Figure 9 is an elevated perspective view of the ear coupler in accordance with a preferred embodiment of the present invention, with the ATA.

Figure 10 is an elevated perspective view of the ear coupler in accordance with a preferred embodiment of the present invention, with the ATA, from the opposite perspective of Figure 9.

25 Figure 11 shows movement of the ATA between the up and down positions.

Figure 12 shows the ear coupler in accordance with a preferred embodiment of the present invention being worn by an infant, with the ATA in both the up and down

1 positions.

5.) Detailed Description

The present invention comprises a one-piece, transparent ear coupler body, 10, with an annular side wall, 20, a bottom wall, 30, an internal chamber, 40, a peripheral flange, 50, a port, 60, an ATA, 70, and a tab, 80. Various aspects and features of the 5 preferred embodiment of this invention are described below.

The ear coupler body, 10, is generally D-shaped, and sized to fit an infant's ear. It is made of a flexible, transparent, smooth, non-crumbly, nonporous material, preferably Rimflex®, which is available from Bay State Polymer Distribution, Inc., P.O. 10 Box 40055, Bay Village, Ohio 44140. Other suitable materials include Kraton, PVC, polyurethane, and Engage. By using a transparent material, the ear coupler can more easily and accurately be placed over the subject's ear. Opaque materials can be used to create the desired acoustic environment, but they do not allow the clinician to visualize the placement of the coupler over the center of the subject's ear.

15 Preferably, the ear coupler is comprised of one-piece, which may result in lower manufacturing costs compared with multi-piece couplers. However, the coupler can be composed of more than one piece, so long as the pieces or their connections are flexible enough so that ear coupler can accommodate the irregular and curved shape of a subject's head. The ear coupler can be made by injection molding, thermoforming, and 20 other processes. The ear coupler is not "handed," meaning that it can fit on either the right or left ear. The ear coupler is provided clean, and can be sterilized as needed for certain applications. The ear coupler is designed to be disposable.

25 The annular side wall, 20, forms a ring around the internal portion of the ear coupler. Preferably, the annular side wall forms a D-shaped ring, although other shapes could be used. The D-shape helps to orient placement of the coupler, so that it is placed with the ATA providing the stimulus from the front of the ear. The annular side

1 wall contains two or more ribs, 22, that are used to removably latch the ATA in place, as  
described below.

5 The annular side wall should be thick enough to provide crush resistance, and in  
the preferred embodiment is approximately 1/8th of an inch thick. Ribs, 22, can also be  
used to improve crush resistance, but in the preferred embodiment, the annular side  
wall provides sufficient strength on its own. The annular side wall is of uniform  
thickness, except around the port, 60, where it is substantially thinner in order to help  
create the interference fit as described below.

10 The bottom wall, 30, is attached to or integral with the annular side wall. Like the  
annular side wall, the bottom wall is thick enough to resist crushing when the subject  
lies on his or her ear. In the preferred embodiment, the bottom wall is approximately  
1/16th of an inch thick.

15 To improve the acoustics of the ear coupler, the surface (exterior or interior) of  
the bottom wall contains a pattern of surface features, 32. Preferably, these surface  
features are a pattern of cross-hatched protuberances that create a waffle-type surface.  
These surface features add strength and rigidity to the bottom wall, and prevent it from  
vibrating in response to the stimulus. If the bottom wall were subject to vibration, then  
the ear coupler would create different acoustic environments based on whether the  
bottom wall was under pressure or not. For instance, if the subject were lying on his or  
her back, then the bottom wall could vibrate, but if the subject were lying on his or her  
20 side, then the ear coupler could be pressed against the bed, thereby inhibiting vibration.  
By adding the surface features, the ear coupler is not subject to any such vibration  
regardless of the subject's position, and thus the ear coupler creates the consistent and  
predictable acoustic environment needed for accurate hearing screening.

25 The bottom wall also preferably includes a target indicating the center of the  
coupler, to help facilitate proper placement of the coupler over the subject's ear. The  
bottom wall could also be imprinted with text, such as the name or trademark of the

1 company manufacturing or selling the ear coupler.

The chamber, 40, is formed by the annular side wall and the bottom wall, and is sufficiently large to accommodate the subject's ear. The chamber creates a tuned, isolated acoustic chamber, with precise acoustic properties so that hearing screening can be conducted. Aural stimuli are transmitted into the chamber through the port.

5 The flange, 50, extends around the periphery of coupler, projecting out past the annular side wall. The flange may be centered over the internal chamber, or can begin at the annular side wall. The flange can be cut or slit to increase its ability to conform to the subject's head, and indeed, multiple flanges could be used. In the preferred embodiment, as reflected in the drawings, a single unitary flange beginning at the annular side wall is used. The flange should be flexible, so that it can securely attach to the curved and irregular shape of a subject's head.

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10 The flange is relatively planar or smoothly tapered, but may have barriers at the inner and outer periphery to help contain the adhesive. In the preferred embodiment, these barriers take the form of slight ridges that prevent overflow when the flange is coated with adhesive during manufacture.

15 The preferred adhesive is hydrogel, although other adhesives could be used so long as they allow the coupler to be removably attached to the subject's head. Previous ear couplers have used a laminate for adhesion, which resulted in wasted material, since the adhesive pattern had to be punched from a sheet of hydrogel material. Under the 20 present invention, the hydrogel is selectively applied only to the flange, and then placed on the release paper, resulting in minimal waste.

25 The flange, coated with adhesive, is the preferred structure to removably attach the ear coupler to the subject's head. However, if a flange is not used, then the ear coupler could be attached to the subject's head by any number of conventional means, such as tape, clips, a headband, or adhesive applied to the periphery of the coupler or to a flexible extension attached to the periphery.

1        The hydrogel may have a pattern of surface features, 52, on the surface that  
contacts the infant's head. These surface features may improve adhesion of the flange  
to the Rimflex®, although they are not present in the preferred embodiment of this  
invention.

5        The flange extends from the annular side wall a sufficient distance for proper  
adhesion. In a preferred embodiment of present invention, the flange extends  
approximately 1/4 inch from the annular side wall.

10      The port, 60, is an opening in the annular side wall for placement of the ATA, 70.  
Preferably, the port is sized to create an interference fit with the ATA, so that there is  
some initial resistance when placing the ATA in the port, and then there is a click or  
snap when the ATA is pushed into place. For purposes of this patent, "interference fit"  
denotes the fit between the ATA and the port, whereby there is initial resistance and  
then relief once the ATA snaps into place. The tip of the ATA is barbed to facilitate  
insertion into the port. Preferably, when placed on the infant's head, the port will face  
the front or tragus side of the infant's ear, which corresponds to the flat portion of the  
"D" shaped coupler.

20      The ATA, 70, is an assembly that houses a transducer for generating the aural  
stimuli. It also may house other devices such as a microphone for monitoring acoustic  
energy within the environment. The ATA is on the end of a cable, which connects it to  
the hearing evaluation device. The ATA snaps into the port, and may be positioned in  
either an up or a down position, along the side of the ear coupler, as illustrated in Figs.  
25      11 & 12. The ATA can be rotated between the up and down positions during screening,  
as shown in Figs. 11 and 12. The ATA also may include a latch that snaps onto to the  
ribs of the annular side wall, helping to ensure that the ear coupler is not tugged away  
from the subject's head. The ATA hugs or mates with the side of the ear coupler, which  
improves crush resistance and prevents the ATA from acting as a lever arm which  
could pull the ear coupler off the subject's head.

1        The tab, 80, is attached to or integral with the flange, and is used to help remove  
the ear coupler from the infant's head. Preferably, the tab, 80, is placed opposite to the  
port, 60, but could be placed anywhere on the periphery of the flange. The tab is also  
useful in removing the ear coupler from the release paper.

5        Before use, the ear coupler is provided to the user attached to release paper, to  
help ensure cleanliness and to preserve the sticking power of the adhesive. Holes may  
be placed in the portion of the release paper facing the bottom wall, to make it easier to  
hold the coupler while inserting the ATA.

10       In operation, the ATA, 70, is inserted into the port, 60, and snapped onto the ribs  
in either the up or down position, depending on the operator's preference. The ear  
coupler, 10, is then removed from the release paper and placed on the subject's head, so  
as to cover his or her ear. The adhesive on the flange, 50, holds the coupler in place  
during testing. As necessary, the ATA can be flipped from the up or down position  
during testing to accommodate the particular position of the subject. After testing, the  
ear coupler is removed, using the tab.

15       The present ear coupler is much less likely to become detached during testing  
than previous couplers, since its flexible, one-piece body can better accommodate the  
irregular and curved shape of the subject's head. It also is better able to move and  
stretch as necessary in response to the subject's movements.

20       The present ear coupler is also less costly to manufacture, since it is preferably  
made of one-piece, and can be created using relatively inexpensive processes such as  
injection molding and thermoforming.

25       The ear coupler can be used for hearing screening of infants, children, or adults,  
and can also be used as a sound-blocking "ear muff," when a quiet acoustic  
environment is desired.

One skilled in the art will appreciate that the present invention can be practiced  
by other than the described embodiments, which are presented for purposes of

1 illustration and not limitation. The particular dimensions and materials recited herein  
are presented for purposes of illustration and not limitation.

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